GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2653
ANSWERED ON:17.03.2017
Vaccination in India
Mani Shri Jose K.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware that the World Health Organisation (WHO) has given the Indian vaccine regulatory structure the highest possible rating of 4 on a majority of parameters, if so, the details thereof;

(b) whether experts in multiple disciplines drawn from WHO's Geneva headquarters from US, Italy, Germany and Netherlands visited India recently to assess the National Regulatory Authority of India, if so, the details thereof; and

(c) whether with this rating, India has been classified as a stringent regulator of vaccines alongside developed countries such as US, Japan and EU member States and if so, the details thereof?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a): Indian Vaccine Regulatory System was assessed by WHO against Global Benchmarking Tool (GBT) comprising 9 functions for measuring the maturity of Indian Vaccine Regulatory System viz. National Regulatory System; Registration & Marketing Authorization; Vigilance; Market Surveillance & Control; Licensing Premises; Regulatory Inspections; Laboratory Access & Testing; Clinical Trial Oversight; and NRA Lot Release. WHO has given highest possible rating of 4 to Registration & Marketing Authorization; Vigilance; Laboratory Access & Testing; Clinical Trial Oversight; and NRA Lot Release. WHO has given a rating of 3 in respect of the remaining four functions.

(b): The assessment was carried out by a WHO team comprising experts with decades of experience in different areas of Regulatory Systems in Regulatory Agencies, Laboratories & Institutes from WHO Hqrs, WHO India office, USA, Italy, Germany, Netherland, Indonesia, Thailand and Egypt.

(c): Indian National Regulatory Agency has been declared functional by WHO based on the most comprehensive assessment ever carried out by WHO anywhere in the world with 63 indicators and 288 sub-indicators.